

**Amendments to the Claims:**

The listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (original) A method for controlling a fluid separation system comprising:  
triggering a first-level alarm condition in response to a pressure drop to less than or equal to a specified system pressure, said first alarm condition comprising pausing fluid flow in at least a portion of said system for a specified delay time;  
triggering a second alarm condition in response to a specified number of said pressure drops within a specified period, said second alarm condition comprising reducing flow rate of fluid in said system.
2. (original) The method of claim 1 wherein said specified number of specified pressure drops is between about two and about five.
3. (original) The method of claim 2 wherein said specified number of specified pressure drops is about three.
4. (original) The method of claim 1 wherein said specified delay time is between about 2 and about 6 seconds.
5. (original) The method of claim 4 wherein said specified delay time is about 5 seconds.
6. (currently amended) The method of claim 1 wherein said specified ~~pressure drop~~ system pressure in said system is between about -100 and about -250 mmHg.

7. (original) The method of claim 1 wherein said first-level alarm condition comprises sounding an audible alarm and/or displaying a visible alarm.
8. (original) The method of claim 1 wherein said second-level alarm condition comprises sounding an audible alarm and/or displaying a visible alarm.
9. (original) The method of claim 8 wherein said alarm is sounded and/or displayed continuously.
10. (currently amended) The method of claim 1 also comprising returning said flow rate in said system to normal flow rate if pressure in the system rises to a specified first-level alarm-disabling pressure.
11. (currently amended) The method of claim 10 wherein said selected first-level alarm-disabling pressure in the system is between about 0 and about ~~-150 mmHg~~ -150 mmHg.
12. (original) The method of claim 11 wherein said specified first-level alarm-disabling pressure in the system is about -50 mmHg.
13. (original) The method of claim 1 also comprising:  
triggering a third alarm condition in response to failure of pressure in the system to rise to a specified first-level alarm-disabling pressure in the system.
14. (original) The method of claim 1 wherein said fluid separation system is a blood apheresis system.
15. (original) The method of claim 14 wherein said blood apheresis system comprises a leukocyte reduction chamber.

16. (currently amended) The method of claim 44 15 wherein during said first-level alarm condition, flow through said leukocyte reduction chamber is maintained.
17. (original) The method of claim 1 wherein during said second-level alarm condition, said flow rate is low enough to prevent triggering a further first-level alarm condition.
18. (original) The method of claim 17 wherein during said second-level alarm condition, flow in said system is reduced to about one-half normal rate.
19. (original) The method of claim 1 wherein said specified period is between about 1 and about 10 minutes.
20. (original) The method of claim 1 wherein said specified period is about five minutes.
21. (original) The method of claim 1 wherein said reduced flow rate persists for an indefinite period.
22. (original) The method of claim 21 wherein said second-level alarm condition is terminated by an operator by resolving the problem which gave rise to said second-level alarm condition and returning said flow rate to normal.
23. (original) The method of claim 22 wherein said second-level alarm condition is terminated by an operator by shutting down the system.
24. (currently amended) The method of claim 1 wherein said specified system pressure ~~in the system~~ is used to calculate a specified sensor pressure which triggers said first-level alarm by modifying the specified system pressure ~~in the system~~ using selected system parameters.

25. (currently amended) The method of claim 24 wherein said system is a blood apheresis system, and said selected system parameters include ~~inlet pump the hematocrit in the inlet tubing line, ratio of anticoagulant to whole blood in an inlet line of said system during platelet and plasma collection~~ the flow rate in the inlet tubing line, inlet pump flow rate the flow rate in the needle, and donor the hematocrit in the needle.

26. (currently amended) The method of claim 25 wherein said specified sensor pressure is determined by the following formula:

$$P_{AAL} = P_{AALS} + 75 - 0.331 Q_{ININSTD} / (1 - H_{IN}) - 0.303 Q_{ININSTD} (1 - 1/R) / (1 - H) = 350$$

~~where P<sub>AAL</sub> is the specified sensor pressure; P<sub>AALS</sub> is the specified pressure in the system, mmHg; H<sub>IN</sub> is inlet pump hematocrit, decimal; Q<sub>ININSTD</sub> is inlet pump flow rate, ml/min; and R is ratio of whole blood in an inlet line of said system during platelet and plasma collection.~~

$$\text{specified sensor pressure} = \text{Config} + 75 - 0.3309 * Q_{in} / (1 - H_{in}) - 0.3026 * Q_n / (1 - H_n);$$

wherein Config is a configuration specified system pressure (mmHg), Q<sub>in</sub> is the flow rate in the inlet tubing line (ml/min.); H<sub>in</sub> is the Hematocrit in the inlet tubing line; Q<sub>n</sub> is the flow rate in the needle (ml/min.); and H<sub>n</sub> is the Hematocrit in the needle.

27. (original) A method for controlling an apheresis system comprising:  
triggering a first alarm condition in response to a specified pressure drop to less than or equal to a specified pressure in the system, said first alarm condition comprising pausing fluid flow in at least a portion of said system for a specified delay time;

if plasma and platelet collection is incomplete, triggering a second-level alarm condition in response to a specified number of said specified pressure drops within a specified period, said second alarm condition comprising reducing flow rate of fluid in said system;

if plasma and platelet collection is complete, triggering a third-level alarm condition in response to a selected number of said selected pressure drops within a specified period, said third-level alarm condition comprising stopping all pumps.

28. (currently amended) A method for controlling flow rate of return of fluid to a fluid source in a fluid separation process wherein components have been separated from said fluid, said method comprising:

specifying a system return-flow alarm-triggering pressure, and when the pressure of said return flow in the system is higher than or equal to said specified pressure, triggering a return-flow alarm.

29. (original) The method of claim 28 wherein said specified system return flow alarm triggering pressure is used to calculate a specified sensor pressure which triggers said return-flow alarm by modifying the specified pressure in the system using the specified system return-flow alarm-triggering pressure and selected system parameters.

30. (currently amended) The method of claim 29 wherein said system is a single-needle blood apheresis system, and said selected system parameters include return-pump the flow rate in the inlet tubing line, return-pump the hematocrit in the inlet tubing line, return- the flow rate in the needle flow, and return-needle the hematocrit in the needle.

31. (currently amended) The method of claim 30 wherein the specified sensor pressure that triggers the return-flow alarm condition is calculated using the formula:

$$P_{RAL} = P_{RALS} - 50 - 0.3331 Q_{ININSTR} / (1 - H_{IN}) - 0.303 Q_{NRET} / (1 - H_{NRET}) = 400$$

~~where  $P_{RAL}$  is the sensor pressure that triggers the return pressure alarm, mmHg;  $P_{RALS}$  is the specified system return flow alarm triggering pressure, mmHg;  $Q_{ININSTR}$  is return pump flow, ml/min;  $H_{IN}$  is return pump hematocrit, decimal;  $Q_{NRET}$  is the flow rate through the needle during the single needle return phase, ml/min; and  $H_{NRET}$  is the hematocrit of the flow through the return needle~~

$$\text{specified sensor pressure} = \text{Config} - 50 - 0.3309 * Q_{in} / (1 - H_{in}) \\ - 0.3026 * Q_n / (1 - H_n);$$

wherein Config is a configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.

32. (original) The method of claim 28 wherein said return-flow alarm comprises stopping of said return fluid.
33. (original) The method of claim 32 wherein said return-flow alarm comprises sounding an audible alarm and/or displaying a visible alarm.
34. (currently amended) The method of claim 32 wherein said specified system return-flow alarm-triggering pressure is between about 100 and about 310 ~~mgHg~~ mmHg

35. (original) A fluid separation control system comprising:
- pumps for moving fluid through said system;
  - a fluid pressure monitoring device for sensing fluid pressures in said system and generating pressure signals in response to said sensed pressures;
  - a processor for receiving said pressure signals and generating alarm-triggering signals in response thereto;
  - an audible and/or visible alarm triggered by said alarm-triggering signals;
  - and
  - a flow controller triggered by said alarm-triggering signals;
- wherein said processor is programmed to compare said sensed pressures with system pressures and generate a first-level alarm-triggering signal when said sensed pressures are less than or equal to a first-level alarm-triggering sensor pressure;
- wherein said first-level alarm-triggering signal causes said flow controller to pause fluid flow in some of said pumps for a specified delay time;
- wherein said processor is programmed to count the number of first-level alarm-triggering signals generated within a specified period and generate a second-level alarm-triggering signal when a specified number of such first-level alarm-triggering signals have been generated within said specified period; and
- wherein said second-level alarm-triggering signal causes said flow controller to slow down fluid flow rate in said system.
36. (original) The control system of claim 35 wherein said alarm responds to said first-level alarm-triggering signal by sounding an audible alarm and/or displaying a visible alarm.
37. (original) The control system of claim 35 wherein said alarm responds to said second-level alarm-triggering signal by continuously sounding an audible alarm and/or continuously displaying a visible alarm.

38. (currently amended) The fluid separation control system of claim 35 wherein said processor is programmed to calculate said first-level alarm-triggering sensor pressure level using a specified system pressure and selected system parameters.
39. (currently amended) The fluid separation control system of claim 38 designed to control a blood apheresis system, wherein said system parameters comprise inlet pump the hematocrit in the tubing line, ratio of anticoagulant to whole blood in an inlet line of said system during platelet and plasma collection the flow rate in the inlet line, inlet pump flow rate the flow rate in the needle, and donor the hematocrit in the needle.
40. (currently amended) The fluid separation control system of claim 39 wherein said processor is programmed to calculate said calculated first-level alarm-triggering pressure by using the following formula:

$$P_{AAL} = P_{AALS} + 75 - 0.331 Q_{ININSTD} / (1 - H_{IN}) - 0.303 Q_{ININSTD} (1 - 1/R) / (1 - H) = 350$$

where  $P_{AAL}$  is the specified sensor pressure;  $P_{AALS}$  is the specified system pressure, mmHg;  $H_{IN}$  is inlet pump hematocrit, decimal;  $Q_{ININSTD}$  is instantaneous inlet pump flow rate, ml/min; and  $R$  is ratio of whole blood to anticoagulant in an inlet line of said system during platelet and plasma collection.

$$P_{1st\ level\ alarm} = Config + 75 - 0.3309 * Q_{in}/(1-H_{in}) - 0.3026 * Q_n/(1-H_n);$$

wherein  $P_{1st\ level\ alarm}$  is the first level alarm-triggering sensor pressure; Config is a configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.



41. (currently amended) The fluid separation control system of claim ~~39~~ 38 wherein said specified system pressure is between about -100 and -250 mmHg.
42. (original) The control system of claim 35 wherein said processor is programmed to compare said sensed pressures with a selected first-level alarm-disabling pressure.
43. (currently amended) The control system of claim ~~[[44]]~~ 42 wherein said processor is programmed to generate a first-level alarm-disabling signal if the sensed pressure rises to a value greater than or equal to a specified first-level alarm-disabling sensor pressure within the specified delay time; and  
wherein the flow controller responds to said first-level alarm-disabling signal by causing pumps which were paused to resume pumping.
44. (original) The control system of claim 42 wherein said processor is programmed to calculate said first-level alarm-disabling pressure using a specified alarm-disabling system pressure and selected system parameters.
45. (original) The control system of claim 44 wherein said specified alarm-disabling system pressure is between about 0 and about -150 mmHg.
46. (original) The control system of claim 44 wherein said specified alarm-disabling system pressure is about -50 mmHg.
47. (original) The control system of claim 43 wherein said alarm responds to said first-level alarm-disabling signal by stopping sounding and/or displaying the alarm.
48. (original) The control system of claim 43 wherein said processor is programmed to generate a third-level alarm-triggering signal if the sensed pressure does not

rise to a value greater than or equal than the specified first-level alarm-disabling sensor pressure within the specified delay time; and

wherein the flow controller responds to said third-level alarm-triggering signal by shutting down all pumps in the system.

49. (original) The control system of claim 48 wherein said alarm responds to said third-level alarm-triggering signal by sounding an audible alarm and/or displaying a visible alarm.
50. (original) The control system of claim 35 wherein said specified number of first-level alarm-triggering signals is between about two and about five.
51. (original) The control system of claim 50 wherein said specified number of first-level alarm-triggering signals is about three.
52. (original) The control system of claim 35 wherein said specified delay time is between about 2 and about 6 seconds.
53. (original) The control system of claim 52 wherein said specified delay time is about 5 seconds.
54. (original) The control system of claim 39 wherein said blood apheresis system comprises a leukocyte reduction chamber.
55. (currently amended) The control system of claim 54 wherein said flow controller does not pause fluid flow through said ~~said~~ leukocyte reduction chamber in response to said first-level alarm-triggering signal.
56. (original) The control system of claim 35 wherein said flow controller slows said flow rate in response to said second-level alarm-triggering signal to a rate low enough to prevent triggering a further first-level alarm condition.

57. (original) The control system of claim 35 wherein said flow controller slows said rate to about one-half normal rate.
58. (original) The control system of claim 35 wherein said flow controller maintains said reduced flow rate until an operator operates said flow controller to return said flow rate to normal or to shut down all of said pumps.
59. (original) The control system of claim 35 wherein said specified period is between about 1 and about 10 minutes.
60. (original) The control system of claim 35 wherein said specified period is about five minutes.
61. (original) The control system of claim 35 also comprising a process monitor for assessing completeness of collection of platelets and plasma; said processor being in signal communication with said process monitor, and being programmed to trigger a second-level alarm condition only if collection of platelets and plasma is incomplete.
62. (original) A fluid separation control system comprising a pump for returning fluid to a fluid source, said control system comprising:
  - a fluid pressure monitoring device for sensing return fluid pressures in said system and generating return pressure signals in response to said sensed return fluid pressures;
  - a processor for receiving said return fluid pressure signals and generating a return-alarm-triggering signal in response thereto;
  - a flow controller triggered by said return-alarm-triggering signal;
  - wherein said processor is programmed to compare said sensed pressures with system return pressures and generate a return alarm-triggering signal when said sensed pressures are greater than or equal to a specified system return alarm-triggering pressure;

wherein said return alarm-triggering signal causes said flow controller to stop all pumps.

63. (original) The control system of claim 62 also comprising an alarm responsive to said return alarm-triggering signal which sounds an audible alarm or displays a visible alarm.
64. (original) The control system of claim 62 which is a blood apheresis system.
65. (currently amended) The control system of claim 62 wherein said specified return-flow alarm-triggering pressure is between about 100 and about 310 ~~mgHg~~ mmHg.
66. (new) The method of claim 25 wherein said specified sensor pressure that triggers the return-flow alarm condition is calculated using the formula:

$$\begin{aligned} \text{specified sensor pressure} = & \text{Config} + 75 - 0.3309 * Q_{in}/(1-H_{in}) \\ & - 0.5602 * Q_n/(1-H_n); \end{aligned}$$

wherein Config is a configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.

67. (new) The method of claim 30 wherein said specified sensor pressure is determined using the following formula:

$$\begin{aligned} \text{specified sensor pressure} = & \text{Config} - 50 - 0.3309 * Q_{in}/(1-H_{in}) \\ & - 0.5602 * Q_n/(1-H_n); \end{aligned}$$

wherein Config is a configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.

68. (new) The fluid separation control system of claim 39 wherein said processor is programmed to calculate said calculated first-level alarm-triggering pressure using the following formula:

$$\begin{aligned} \text{specified sensor pressure} = & \text{Config} + 75 & - 0.3309 * Q_{in}/(1-H_{in}) \\ & & - 0.5602 * Q_n/(1-H_n); \end{aligned}$$

wherein Config is a configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.